



Robert Greene Steme Edward J. Kessler Jorge A. Goldstein David K.S. Cornwe Robert W. Esmond Tracy-Gene G. Durkin Michele A. Cimbala Michael B. Ray Robert E. Sokohl Eric K. Steffe Michael Q. Lee Steven R. Ludwig John M. Covert Linda E. Alcom Robert C. Millonig Donald J. Featherstone Lawrence B. Bugaisky Michael V. Messinger

Judith U. Kim Timothy J. Shea, Jr. Patrick E. Garrett Heidi L. Kraus Edward W. Yee Albert L. Ferro Albert L. Ferro Donald R. Banowit Peter A. Jackman Teresa U. Medler Jeffrey S. Weaver Kendrick P. Patterson Vincent L. Capuano Eldora Ellison Floyd Thomas C. Fiala

June 10, 2004

Tiera S. Coston Aric W. Ledford

Elizabeth J. Haanes Joseph S. Ostroff Frank R. Cottingham Christine M. Unulier Rae Lynn Prengaman Jane Shershenovich' George S. Bardmesser Daniel A. Klein' Jason D. Eisenberg Michael D. Specht Andrea J. Kamage Tracy L. Muller' Tracy L. Muller* LuAnne M. DeSantis John J. Figueroa Ann E. Summerfield

Timothy A. Doyle* Gaby L. Longsworth* Nicole D. Dretar* Ted J. Ebersole Jyoti C. Iyer*

Registered Patent Agents • Karen R. Markowicz Nancy J. Leith Helene C. Carlson Matthew J. Dowd Aaron L. Schwartz Katrina Y. Pei Quach Bryan L. Skelton Robert A. Schwartzman Teresa A. Colella Jeffrey S. Lundgren Victoria S. Rutherford

Eric D. Hayes Michelle K. Holoubek Robert H. DeSelms Simon J. Elliott Julie A. Heider Mita Mukherjee Scott M. Woodhouse

Of Counsel Kenneth C. Bass III Evan R. Smith Marvin C. Guthrie

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WRITER'S DIRECT NUMBER: (202) 772-8615 INTERNET ADDRESS: FRANKC@SKGF.COM

Art Unit 1653

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/612,410; Filed: July 3, 2003

Methods and Compositions for the Production, Identification and

Purification of Fusion Proteins

Inventor:

Robert P. Bennett

Our Ref:

0942.5510003/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Information Disclosure Statement;
- 2. Listing of the cited documents on Form PTO-1449 (21 sheets);
- 3. Copies of the cited documents (except AA1-AB3); and
- One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

Frank R. Catter

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham

Attorney for Applicant

Registration No. 50,437

FRC/shr Encls.

SKGF 272260.1

Sterne, Kessler, Goldstein & Fox P.L.C. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : www.skgf.com



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Robert P. Bennett

Appl. No.: 10/612,410

Filed: July 3, 2003

For: Methods and Compositions for the Production, Identification and Purification of Fusion Proteins

Confirmation No.: 3567

Art Unit: 1653

Examiner: To be assigned

Atty. Docket: 0942.5510003/RWE/FRC

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§1.56, 1.97 and 1.98.

A copy of documents **AA1** to **AB3** is not provided in accordance with the U.S. Patent and Trademark Office OG notice of August 5, 2003, which states "[t]he Office hereby waives the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication filed after June 30, 2003." Copies of all other cited documents are provided.

The Examiner is referred to the following list of related, co-pending patent applications:

U.S. Patent Application No. 09/732,914, filed December 11, 2000, inventors Cheo et al., Pub. No. 2002/0007051 A1, listed herewith as Document AK2;

- U.S. Patent Application No. 10/005,876, filed December 7, 2001, inventors Chesnut *et al.*, Pub. No. 2003/0186233 A1, listed herewith as Document **AB3**;
- U.S. Patent Application No. 09/438,358, filed November 12, 1999, inventors Gerard *et al.*, submitted herewith as Document **AR21**;
- U.S. Patent Application No. 09/517,466, filed March 2, 2000, inventors Hartley et al., submitted herewith as Document AS21;
- U.S. Patent Application No. 09/695,065, filed October 25, 2000, inventors Brasch *et al.*, submitted herewith as Document **AT21**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham Attorney for Applicant Registration No. 50,437

Frank R. Catti

Date: <u>June 10, 2004</u>

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

FILING DATE **ART UNIT** July 3, 2003 1653 **U.S. PATENT DOCUMENTS EXAMINER** DOCUMENT INITIAL **CLASS** NUMBER DATE NAME SUB-CLASS **FILING DATE** AA1 4,889,818 12/26/1989 Gelfand et al. 06/17/1987 AB1 4,965,188 10/23/1990 Mullis et al. 06/17/1987 AC₁ 5,047,342 09/10/1991 Chatterjee 08/10/1989 AD1 5,079,352 01/07/1992 Gelfand et al. 05/15/1990 AE1 5.244,797 09/14/1993 Kotewicz et al. 03/18/1991 AF1 5,252,466 10/12/1993 Cronan, Jr. 05/18/1990 AG1 5,270,179 12/14/1993 Chatteriee 01/28/1992 AH1 5,374,553 12/20/1994 Gelfand et al. 08/13/1990 Barnes AI1 5,436,149 07/25/1995 02/19/1993 AJ1 5,512,462 04/30/1996 Cheng 02/25/1994 AK1 5,614,365 03/25/1997 Tabor et al. 11/10/1994 **FOREIGN PATENT DOCUMENTS** EXAMINER DOCUMENT NUMBER INITIAL DATE COUNTRY **CLASS** SUB-CLASS **TRANSLATION** Yes AL1 WO 92/06188 A2 · 04/16/1992 **WIPO** No Yes WO 92/06200 A1 AM1 **WIPO** 04/16/1992 No Yes AN1 WO 96/10640 A1 04/11/1996 **WIPO** No Yes AO1 WO 96/19497 A1 · 06/27/1996 **WIPO** No Yes **WIPO** AP1 WO 97/09451 A1 " 03/13/1997 No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Airenne, K.J., et al., "Avidin Is a Promising Tag for Fusion Proteins Produced in Baculovirus-Infected Insect Cells," Protein Expr. Purif. 17:139-145, Academic Press (1999) AR 1 Andersen, A.H., et al., "Studies of Topoisomerase II-mediated Cleavage and Religation Reactions by Use of a Suicidal Double-stranded DNA Substrate," J. Biol. Chem. 266:9203-9210, The American Society for Biochemistry and Molecular Biology, Inc. (1991) AS 1 Andersson, S., et al., "Cloning, Structure, and Expression of the Mitochondrial Cytochrome

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	ATTY. DOCKET NO. 0942.5510003/RWE/FRC	APPLICATION NO. 10/612,410	
FORM PTO-1449	FIRST NAMED INVENTOR		•
	Robert P. Bennett		
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	ATTY. DOCKET NO. 0942.5510003/RWE/FRC	APPLICATION NO. 10/612,410
FORM PTO-1449	FIRST NAMED INVENTOR	
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INFORMATION DISCLOSURE STATEMENT	FILING DATE	ART UNIT
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	AR	9	Jank, M.M.,	, et al., "Expre	ession and Biotinylation o " <i>Protein Expr. Purif. 17</i> :1	f a Mutant of the Tran	scarboxylase Ca	arrier Protein
	AS	9	DNA Topois	and Wang, J.0 somerase," <i>J.</i> Biology, Inc. (1	C., "Identification of the Yo. <i>Biol. Chem.</i> 267:17178-11992)	east <i>TOP3</i> Gene Prod 17185, The American	duct as a Single Society for Bioc	Strand-specific hemistry and
	АТ	9			olation of cloned Moloney Nucl. Acids Res. 16:265-2			riptase lacking
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	ATTY. DOCKET NO. 0942.5510003/RWE/FRC	APPLICATION NO. 10/612,410
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	AR	10	Landy, A. FLP," Cu.	, "Mechanistic a rr. Opin. Genet.	nd structural complexity Dev. 3:699-707, Current	in the site-specific re Biology, Ltd. (1993)	combination pat	hways of Int an
	AS	10	Thermus	aquaticus DNA l	-level Expression, Purifi Polymerase and a Trunc 87, Cold Spring Harbor I	cated Form Deficient	in 5' to 3' Exonu	on of Full-length clease Activity,"
	АТ	10	Topoison	al., "The traE Ge terase III," <i>J. Bio</i> Biology, Inc. (19	ne of Plasmid RP4 Enco II. Chem. 272:19582-195 997)	odes a Homologue of 587, The American So	Escherichia coli ociety for Bioche	DNA mistry and
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	ATTY. DOCKET NO. 0942.5510003/RWE/FRC	APPLICATION NO. 10/612,410	<u> </u>
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	AR	11	Manstein, [D.J., et al., "Clo	ning vectors for the pro er Science B.V. (1995)	oduction of proteins in	Dictyostelium d	scoideum,"
	AS	11	Mills, A.A., Cold Spring	"Changing colo Harbor Labora	ors in mice: an inducible atory Press (June 2007)	e system that delivers 1)	," Genes Dev. 1	5:1461-1467,
	AT	11	Murray, P.J Facilitate A (1995)	l., <i>et al</i> ., "Epitop nalysis of BiP -	e Tagging of the Hum Substrate Interactions	an Endoplasmic Retic s," <i>Anal. Biochem.</i> 229	ulum HSP70 Pr 9:170-179, Acade	otein, BiP, to emic Press, Inc.
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	AS	12	the Human	, <i>et al.</i> , "Nega Cytomegalovi Microbiology (ative and Positive Regula irus Major Immediate-Ear (1987)	tion by a Short Segm ly Gene," <i>Mol. Cell B</i>	ent in the 5'-Fla iol. 7:4125-4129	nking Region of), American
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	АТ	13	Roca, J., a A Key Step	nd Wang, J.C., ' in DNA Transp	The Capture of a DNA ort by Type II DNA Top	Double Helix by ar oisomerases," <i>Celi</i>	ATP-Dependent 71:833-840, Cell	Protein Clamp: Press (1992)
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	AR	14	Rosano, C., Science B.V	<i>et al</i> ., "The X-ra /. (1999)	y three-dimensional structure	of avidin," <i>Bi</i>	omol. Eng. 16:5	-12, Elsevier
	AS	14		A.H., <i>et al.</i> , "Vec 5-135, Elsevier (ctors for selective expression (1987)	of cloned DN	As by T7 RNA p	oolymerase,"
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	AR	<u>15</u>	Spring Hard	or, NY, pp. 16.	30-16.55 (1989)				
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			5:521-527, 6	<i>t al</i> ., "Site-spec Current Biology	ific recombination: devel , Ltd. (1994)	opments	and applic	ations," <i>Curr. Of</i>	oin. Biotech.
	AS	<u>15</u>		-	•				
			Shuman, S.	, and Moss, B.,	"Identification of a vaccing Acad. Sci. USA 84:7478	nia virus	gene enco	ding a type I DN	A
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	AS	<u>16</u>	Topoisomer		ch to Molecular Cloning and Polem. 269:32678-32684, The Am 4)			
	AT	<u>16</u>			DNA topoisomerase: a model e 7, Elsevier Science B.V. (1998)		pe IB enzyme,"	Biochim.
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	ATTY. DOCKET NO. 0942.5510003/RWE/FRC	APPLICATION NO. 10/612,410	
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	AR	17	pneumoniae Biology, Inc.	e," J. Biol. Chem. . (1988)	lium Ion Translocating Oxalace 263:9640-9645, The America	n Society for	Biochemistry a	nd Molecular
	AS	17	Smith, T.F., a Academic Pr	and Waterman, I ress, Inc. (1981)	M.S., "Comparison of Biosequ	ences," <i>Adv</i> .	Appl. Math. 2:4	82-489,
	АТ	<u>17</u>	RNaseH eng		d purification and characterisat porate a C-terminal tripeptide (B.V. (1991)			
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	AR	<u>18</u>	Studier, F.W	., and Moffatt, B	.A., "Use of Bacteriophage T Senes," <i>J. Mol. Biol. 189</i> :113-	7 RNA Polym	erase to Direct	Selective High- ondon) Ltd.
	AS	18	Studier, F.W Enzymol. 18	., <i>et al.</i> , "Use of <i>1</i> 5:60-89, Acaden	T7 RNA Polymerase to Direc nic Press, Ltd. (1990)	t Expression	of Cloned Gene	s," Meth.
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	AS	19	Wilchek, M Academic	M., and Bayer, I Press, Inc. (19	E.A., "Introduction t 90)	o Avidin-Biotin	Technology,	" Methods Enzy	mol. 184:5-13,
	AT	19	Wilson, T. 275:1533-	M., <i>et al.</i> , "Clor 1540, The Ame	ning and Characteri erican Society for B	zation of Droso iochemistry and	phila Topois d Molecular I	omerase IIIβ," J Biology, Inc. (20	. Biol. Chem. 00)
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	Zhang, H.L., <i>et al.</i> , " <i>Escherichia coli</i> DNA Topoisomerase III Is a Site-specific DNA Binding Protein That Binds Asymmetrically to Its Cleavage Site," <i>J. Biol. Chem. 270</i> :23700-23705, The American Society for Biochemistry and Molecular Biology, Inc. (1995)						ding Protein That rican Society for	
	AS	20	Zou, H., et al., "Affinity membrane chromatography for the analysis and purification of proteins Biochem. Biophys. Methods 49:199-240, Elsevier Science B.V. (October 2001)					proteins," J.
	AT	20	Zusman, R., and Zusman, I., "Glass fibers covered with sol-glass as a new support for affinity chromatography columns: a review," <i>J. Biochem. Biophys. Methods 49</i> :175-187, Elsevier Science B.V. (October 2001)					
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	AS	21	Copy of co-pending U.S. Application No. 09/517,466, inventors Hartley et al., filed on March 2, 2000					
	AT	21	Copy of co-pending U.S. Application No. 09/695,065, inventors Brasch et al. filed on October 25, 2000					
EXAMINER						DATE	CONSIDERED	
EXAMINER: Initiation and not conside	itial if refe red. Inclu	rence co	nsidered, whe	ether or not citation	n is in conformance with Mication to Applicant.	PEP 609. Draw line three	ough citation if no	in conformance